DEC 2 2 2010

510(k) Summary
21 CFR 807.92

Ponsky* Non-Balloon Replacement Gastrostomy Tube

Prepared October 19, 2010

General Provisions	Submitter of 510(k) Premarket Notification:	Bard Access Systems, Inc. [Subsidiary of C.R. Bard, Inc.] Salt Lake City, Utah 84116 Phone: (801) 522-5675 Fax: (801) 522-5425
	Contact Person:	Ji Hyun Kim
	Device Trade Name:	Ponsky* Non-Balloon Replacement Gastrostomy Tube
	Device Generic Name:	Gastrointestinal tube and accessories
Subject Device	Trade Name:	Ponsky* Non-Balloon Replacement Gastrostomy Tube
	Common Name:	Gastrointestinal tube and accessories
	Classification Name:	Gastrointestinal tube and accessories (21 CFR 876. 5980, Product Code KNT), Class II
	Classification Panel:	Gastroenterology / Urology
Predicate Device	Trade Name:	Bard* Non-Balloon Replacement Gastrostomy System
	Common Name:	Gastrointestinal tube and accessories
	Classification Name:	Gastrointestinal tube and accessories (21 CFR 876. 5980, Product Code KNT), Class II
	Classification Panel:	Gastroenterology / Urology
	Premarket Notification:	K915837 (Concurrence Date: 03/23/1993)
Device Description	The Ponsky* Non-Balloon Replacement Gastrostomy Tube is a 20 French soft, silicone gastrostomy tube and internal retention dome with pre-attached external bolster and dual port feeding adaptor, packaged sterile with procedural aids. The Ponsky* Non-Balloon Replacement Gastrostomy Tube has a pocket in the dome that fits the obturator in order to assist in placement of the device through an established stoma. The Ponsky* Non-Balloon Replacement Gastrostomy Tube has a feeding port to administer nutrition, and a medication port.	

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Indications for Use	For percutaneous placement of a long-term replacement gastrostomy feeding and/or decompression device into an established stoma.
Intended use	Intended for establishment of replacement gastrostomy through an existing healed stoma resulting from a previously placed gastrostomy tube.
Technological Characteristics	The subject Ponsky* Non-Balloon Replacement Gastrostomy Tube has the same Technological characteristics as the predicate device. There are no new questions raised regarding safety or effectiveness of the device.

Performance Data Assessment

Design verification and validation have been performed in accordance with 21 CFR 820.30, Design controls. The following FDA recognized standards and national standards were referenced to develop in-house test protocols to determine appropriate methods for evaluating the performance of the subject device:

AAMI / ANSI / ISO 10993-1	2003	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
EN 1615	2000	Enteral Feeding Catheters and Enteral Giving Sets for Single Use and Their Connectors
EN 1618	1997	Catheters other than Intravascular Catheters – Test Methods for Common Properties
JIS T 3213	2005	Enteral Feeding Catheters and Enteral Giving Sets
ASTM F 640	2007	Standard Test Methods for Determining Radiopacity for Medical Use
ISO 14971	2009	Medical devices - Application of risk management to medical devices
AAMI / ANSI / ISO 11607-1	2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 3ed. (Sterility)
ANSI / AAMI / ISO 11135	2007	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
AAMI / ANSI / ISO 10993-7	1995 (R) 2001	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Ponsky* Non-Balloon Replacement Gastrostomy Tube meets the pre-determined requirements under 21 CFR 820.30, Design controls, and demonstrates that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dennis Salzmann, Ph.D.
Director, Regulatory Affairs
Bard Access Systems, Inc.
C. R. Bard, Inc.
605 North 5600 West
SALT LAKE CITY UT 84116

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Re: K103109
Trade/Device Name: Ponsky* Non-Balloon Replacement Gastrostomy Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 24, 2010
Received: November 26, 2010

Dear Dr. Salzmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

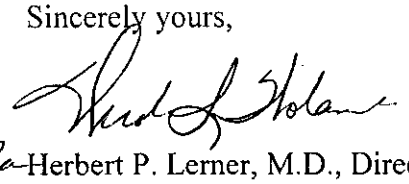
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K103109 DEC 2 2 2010

Device Name: Ponsky* Non-Balloon Replacement Gastrostomy Tube

Indications for Use:

For percutaneous placement of a long-term replacement gastrostomy feeding and/or decompression device into an established stoma.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K103109

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